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| EXAMINER |
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NGUYEN, THONG Q

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| ART UNIT | PAPER NUMBER |
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06/09/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/522,924 | Applicant(s) SHARPE, JAMES ALEXANDER | |
| | Examiner Thong Nguyen | Art Unit 2872 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005 and 20 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/20/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Pre-amendment

1. The present Office action is made in response to the pre-amendment filed on 1/25/2005 and the election filed on 4/20/2010.
2. It is note that in the pre-amendment, applicant has amended claims 3, 6 and 8 and canceled claims 11-12. There is not any claim being added into the application. As a result of the change to the claims. The application now contains claims 1-10. It is also noted that in the pre-amendment, applicant has stated that a substitute specification is filed.
3. A review of the pre-amendment has resulted that applicant has failed to provide a marked up copy of the specification and a statement that the substitute specification does not contain any new matter. In the election filed on 4/20/2010, applicant has submitted a substitute specification and a marked-up copy showing the changes to the specification. However, applicant has failed to file a statement that the substitute specification does not contain any new matter as required by rule 37 CFR 1.125.

Election/Restrictions

4. Applicant's election of species (I) in the reply filed on 4/20/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). As a result of applicant's election, claims 1-9 directed to the elected species (I) are examined in this Office action and claim 10 has been withdrawn from further consideration as being directed to non-elected species.

Priority

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

6. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. See present specification in pages 2-3 and 9, for example.

Drawings

7. The drawings contained four sheets of figures 1, 2a-2b, 3-5, 6a-6d, 7a-7c and 8-12 were received on 1/25/2005. These drawings are objected by the examiner for the following reason(s).

8. Figure 3 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See present specification in page 4 (lines 12) and page 5 (lines 25+). See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified

and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

9. The substitute specification filed on 4/20/2010 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because applicant has not filed a statement that the substitute specification does not contain any new matter.

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

11. The disclosure is objected to because of the following informalities: a) The summary of the invention is objected to because it contains descriptions related to the prior art, see pages 2-3; b) Page 8: on line 14, "zIn" should be changed to --In--. There are some grammatical and idiomatic errors in the specification. Applicant should carefully proofread the specification. Appropriate correction is required.

12. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously

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incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f). See present specification in page 2 (lines 4-7) and page 5 (lines 8-14) and present claims 6-7.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a) Claims 1-2 recite an optical system which is in operative throughout the scanning movement of the light to direct only light exits or by-passed the specimen parallel to the light incident on the specimen to a detector, see claim 1, lines 3-6. The optical system as described in the present specification, in particular, page 5, lines 30+ through page 6, lines 10, is a convex lens which is claimed in the present claim 2. While the present specification discloses that the convex lens of the invention is different from a convex lens of the prior art, see present specification, page 5, lines 25-31; however, the present specification has not provided any description or information related to the structure of the convex lens so that it can provide function/result different from those provided by a conventional convex lens.

b) The remaining claims are dependent upon the rejected base claim and thus inherit the deficiency thereof.

c) Claim 9 is rejected for the similar reason as set forth in element a) above.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 recites the limitations "the scanning movement" on line 4 and "the beam incident" on line 6. There is insufficient antecedent basis for each of the mentioned limitations in the claim.

b) Claim 3 is rejected under 35 USC 112, second paragraph because it is unclear about the feature thereof "the light scanning means form part of a confocal scanning microscope" recited on line 2 of the claim. In other words, it is unclear about the structural relationship between the scanning means of the optical projection tomography apparatus as claimed in present claim 1 and a confocal scanning microscope.

c) Claim 9 recites the limitation "the beam incident" on line 4. There is insufficient antecedent basis for this limitation in the claim.

d) The remaining claims are dependent upon the rejected base claim and thus inherit the deficiency thereof.

Claim Objections

17. Claims 3-5 are objected to because of the following informalities. Appropriate correction is required.

a) In claim 3 (line 2), claim 4 (line 1) and claim 5 (line 1), the term "localised" should be changed to --localized--;

b) In each of claims 4 and 5 (line 2 of each claim), the term "assay" should be changed to --array--.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1-4, 6-7 and 9, as best as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Tsutomu et al (Japanese reference No. 4-122248, submitted by applicant).

Tsutomu et al disclose an optical projection tomography apparatus. The apparatus as described in pages 275-276 and shown in figs 1 and 4 comprises the following features: a) a stage (11) supporting a specimen (S) wherein the stage is able to rotate via a mechanism (9, 10) to bring different sections of the specimen to be illuminated; b) an illuminating system comprises a laser (1) for emitting light to illuminate the sample; c) a scanning means including a deflection mirror (13) and a scanning mirror (14) for scanning the light emitted from the

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laser onto the sample; d) an optical system (3) disposed on the downstream of the light passed through the sample wherein the optical system comprises at least one convex lens, see figure 13 or figure 15 which shows that the optical system (3) comprises at least one biconvex lens; e) a detector (4) disposed on the downstream of the optical system (3) for receiving onto the straight traveling light transmitted through the specimen (S) and focused by the optical system (3). It is noted that the detector (4) as shown in fig. 4 is a linear array of individual detecting elements arranged side-by-side with respect to each other so that when the light is transmitted through the specimen, the particular detecting element which is disposed on the axis of the incident light is a localized detecting element which detects a straight traveling light and the detecting elements disposed on sides of the mentioned particular detecting element detect scattered and/or refracted light. Regarding to the feature related to the positions of the specimen as recited in present claims 6 and 7, such feature is readable from the structure of the apparatus provided by Tsutomu et al. In particular, the mechanism is operated under the control signaled outputted from the data processing device having a three-dimensional calculating unit (8), thus, the rotational positions of the stage are indexed with respect to the raster scanning of the mirror (14) for the purpose of reconstruction a three-dimensional image of the sample.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 5 and 8, as best as understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsutomu et al.

The optical projection tomography apparatus as described in pages 275-277 and shown in figs. 1 and 4 does not disclose that the detector (4) is a two-dimensional array of detectors as recited in present claim 5. However, the use of a two-dimensional array of detector as claimed is merely that of a preferred embodiment and no criticality has been disclosed. The support for that conclusion is found in the present specification in which applicant has disclosed that the detector can be a linear array of detector. The non-criticality of the type of detector as claimed can be seen in present claim 3 which clearly claims that the detector is a linear array of detector. Further, the use of a detector having an array of detecting elements which arrange in a linear array of a two-dimensional array is disclosed by Tsutomu et al as can be seen in page 277 and shown in fig. 7. Thus, absent any showing of criticality, it would have been obvious to one skilled in the art at the time the invention was made to modify the detector in the form of a linear array of detecting elements in the optical projection tomography apparatus as provided by Tsutomu et al as described in the embodiment shown

in fig. 4 by a detector in the form of a two-dimensional array of detecting elements as suggested by the same inventor as shown in fig. 7 for the purpose of meeting a particular application.

Regarding to the feature that the scanning means is a part of a confocal scanning microscope as claimed in present claim 8, such feature would have been obvious to one skilled in the art to utilize the optical projection tomography apparatus having a scanning means (13, 14) in a microscope for the purpose of observation a sample.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thong Nguyen whose telephone number is (571) 272-2316. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephone B. Allen can be reached on (571) 272-2434. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thong Nguyen/

Primary Examiner, Art Unit 2872